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February 24, 2020

Stephen M. Hahn, M.D. Commissioner of Food and Drugs U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

## Dear Commissioner Hahn:

I write today with increasing alarm about the security of our medical product supply chain. The novel coronavirus in China highlights severe, longstanding, and unresolved vulnerabilities in our capacity to produce life-saving pharmaceutical drugs and medical devices for our own citizens. This is unacceptable.

As Axios reported this weekend, the recent outbreak of novel coronavirus has threatened the domestic supply of some 150 prescription drugs, including antibiotics, generics, and branded drugs. Some of these drugs do not have alternatives on the market. The degree to which some of our own manufacturers rely on China to produce life-saving and life-sustaining medications is inexcusable. It is becoming clear to me that both oversight hearings and additional legislation are necessary to determine the extent of our reliance on Chinese production and protect our medical product supply chain.

The FDA plays a key role in ensuring that Americans have safe and uninterrupted access to lifesaving medications and I urge that you take swift action to mitigate these shortages. I request your response within the week to the following questions:

- 1. What actions has the FDA taken to date to ensure that American citizens do not face shortages of life-saving drugs and medical devices?
- 2. What actions will the FDA take in the coming weeks and months to ensure that safe alternatives to any scarce medical products are available for public use?
- 3. What additional resources has the FDA devoted to identifying vulnerabilities in the U.S. medical product supply chain?
- 4. What additional statutory authority, if any, does the FDA need to require information from manufacturers about the sourcing of component parts, active pharmaceutical ingredients, or scarce raw materials in the medical products they produce?
- 5. Will you commit to testifying in congressional hearings about these troubling vulnerabilities in our medical product supply chain and potential policy solutions to keep Americans safe?

Thank you for your work to address this issue.

Sincerely,

Josh Hawley

CC:

The Honorable Alex Azar Secretary Department of Health & Human Services 200 Independence Avenue, SW Washington, DC 20201